International Lyme and Associated Diseases Society

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Connecticut Legislature
Legislative Office Building
Hartford, CT 06106-1591

February 5, 2009

Dear Sir or Madam:

On behalf of the International Lyme and Associated Diseases Society (ILADS), I urge support for Connecticut H.R.6200 bill, "An Act Concerning the Long-term use of Antibiotic Treatment of Lyme Disease." The legislation is urgently needed to ensure that Lyme disease (LD) patients in Connecticut continue to have access to care by physicians experienced in the diagnosis and treatment of chronic Lyme disease (CLD) and to coverage if a physician feels intravenous antibiotics are necessary. This legislation will enable very ill CT residents to choose treatment options that best meet their needs while the medical community works to find consensus on LD treatment guidelines.

The current primary preventive strategies in Connecticut have not reduced the numbers of LD cases. The CDC reported that the average annual rate of 29.2 cases per 100,000 population in ten key states was approximately three times the *Healthy People 2010* target.[1] The actual numbers of cases of LD in Connecticut in 2004 was 1,000 cases per 100,000 based on the following testimony by Dr. Jim Hadler, the state's infectious disease specialist and epidemiologist, "roughly one percent of the entire population or probably 34,000 people are getting a diagnosis of LD in Connecticut each year.... 20 to 25 percent of all families [in Connecticut] have had at least one person diagnosed with Lyme Disease."[2]

All four National Institutes of Health (NIH) sponsored trials validate the severity of CLD.[3-5] Klempner described the Quality of Life (QOL) as "equivalent to those observed in patients with congestive heart failure or osteoarthritis and were more than 0.5 SD greater than the impairment observed in patients with type 2 diabetes or a recent myocardial infarction."[4] I described in a recently published analytic review that the symptoms of CLD were as severe as symptoms seen in other serious chronic illnesses as determined by 22 standardized measures of QOL, including fatigue, pain, role function, psychopathology, and cognition.[6] None of the four RCTs supported the IDSA hypothesis that CLD symptoms are nothing more than, "the aches and pains of

daily living"[7] nor the ad hoc International Lyme group conclusion by Feder in the *New England Journal of Medicine* that CLD symptoms are "symptoms common in persons who have never had Lyme disease."[8]

There were actually modest gains in the NIH sponsored trials.[3-5] The success rates varied from as low as 37% for the two Klempner trials [4] on a QOL scale to as high as 67% for the Krupp and Fallon trials on a fatigue severity scale [3, 5]. The Fallon trials also reported moderate improvements on a cognitive index for both treatment and placebo.[5] I published a trial this year demonstrating that a three month course of oral antibiotics was significantly more effective than placebo.[9]

The risk to society of emerging resistant organisms has not been weighed against the risk to society of an emerging population saddled with CLD.[10] The risk to society of overuse of antibiotics and emergence of multi-resistant infectious disease organisms [11] has received considerable attention. The risk to society of the emerging population of CLD has received less attention. Reports that 34 to 62% of previously treated LD individuals are chronically ill years after antibiotic treatment in the neighboring states of Massachusetts [12] and Westchester [13] respectively reinforce the need to consider the risk of CLD to the individual and the state before denying antibiotics treatment.

The cost of CLD is much more than the direct medical costs according to a 2006 economic study by Zhang and colleagues following collaboration between the CDC, University of Maryland, and a managed health care program in Maryland, USA.[14] Eighty-eight percent of the average annual cost of $16,199 for CLD consisted of indirect medical cost, nonmedical cost, and productivity loss. The approximate annual economic impact of LD in Connecticut is more likely to be ≈$278 million based on the estimation of 34,000 cases every year. The annual cost of ≈$278 million for Connecticut does not include the lifetime pain and suffering for CLD patients, families, and loved ones. Denying intravenous benefits would save at most 12% of the cost of CLD while cutting off an opportunity to resolve the infection.

Without legislation, health insurers could cite the NIH sponsored trials as reason to deny coverage to citizens of Connecticut for CLD.[10, 15] I have attached an epidemiological review recently accepted for publication detailing eight limitations of the evidence used to deny antibiotic coverage: 1) The power of the evidence is inadequate to draw definite conclusions, 2) The evidence is too heterogeneous to make strong recommendations, 3) The risk to an individual of facing a long-term debilitating illness has not been considered, 4) The risk to society of a growing chronically ill population has not been considered, 5) Treatment delay has not been considered as a confounder, 6) Coinfections have not been considered as a confounder, 7) The design of RCTs did not address the range of treatment options in an actual practice, and 8) The findings cannot be generalized to actual practice.

This epidemiological review concluded the following, "This hypothesis suggests that physicians should consider the limitations of the evidence before denying antibiotic

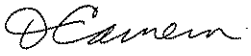
treatment for CLD. Physicians who deny antibiotic treatment to CLD patients might inform their patients that there are some clinicians who disagree with that position, and then offer to refer them for a second opinion to a doctor who could potentially present a different point of view. The hypothesis also suggests that health care insurers should consider the limitations of the evidence before adopting policies that routinely deny antibiotic treatment for CLD patients and should expand coverage of CLD to include clinical discretion for specific clinical situations."[10]

Why do we need legislation for a problem we usually work out in medicine? There are several obstacles to medicine working this out.

- ILADS physicians experienced in the treatment of CLD and citizens of the Connecticut have been excluded from the process of developing guidelines for CLD by the Infectious Diseases Society of America (IDSA),
- CLD patients have been denied access to care based only on the IDSA view, and
- Physicians have been reluctant to treat LD patients based on reports that physicians who treat LD have been subject to professional misconduct proceedings.

ILADS continues to encourage dialogue in the medical community to find common ground for the alarming number of Connecticut residents suffering from CLD. ILADS advises passage of the H.R.6200 to allow Connecticut's residents with CLD insurance coverage and offer some protection for physicians who use their own clinical judgment when treating a CLD patient.

Sincerely



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Attachments:

1. Cameron DJ: **Clinical trials validate the severity of persistent Lyme disease symptoms**. *Med Hypotheses* 2008.
2. Zhang X, Meltzer MI, Pena CA, Hopkins AB, Wroth L, Fix AD: **Economic impact of Lyme disease**. *Emerg Infect Dis* 2006, **12**(4):653-660.
3. Cameron DJ: **Consequences of treatment delay in Lyme disease**. *J Eval Clin Pract* 2007, **13**(3):470-472.

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2. http://www.ct.gov/ag/lib/ag/health/0129lyme.pdf: **Last accessed 12/4/08**. Page 290.
3. Krupp LB, Hyman LG, Grimson R, Coyle PK, Melville P, Ahnn S, Dattwyler R, Chandler B: **Study and treatment of post Lyme disease (STOP-LD): a randomized double masked clinical trial.** *Neurology* 2003, **60**(12):1923-1930.
4. Klempner MS, Hu LT, Evans J, Schmid CH, Johnson GM, Trevino RP, Norton D, Levy L, Wall D, McCall J *et al*: **Two controlled trials of antibiotic treatment in patients with persistent symptoms and a history of Lyme disease**. *N Engl J Med* 2001, **345**(2):85-92.
5. Fallon BA, Keilp JG, Corbera KM, Petkova E, Britton CB, Dwyer E, Slavov I, Cheng J, Dobkin J, Nelson DR *et al*: **A randomized, placebo-controlled trial of repeated IV antibiotic therapy for Lyme encephalopathy**. *Neurology* 2008, **70**(13):992-1003.
6. Cameron DJ: **Clinical trials validate the severity of persistent Lyme disease symptoms**. *Med Hypotheses* 2008.
7. Wormser GP, Dattwyler RJ, Shapiro ED, Halperin JJ, Steere AC, Klempner MS, Krause PJ, Bakken JS, Strle F, Stanek G *et al*: **The clinical assessment, treatment, and prevention of lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the Infectious Diseases Society of America**. *Clin Infect Dis* 2006, **43**(9):1089-1134.
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9. Cameron D: **Severity of Lyme disease with persistent symptoms. Insights from a double-blind placebo-controlled clinical trial**. *Minerva Med* 2008, **99**(5):489-496.
10. Cameron DJ: **Insufficient evidence to deny antibiotic coverage to chronic Lyme disease patients**. *Med Hypotheses* 2009.
11. Levy SB: **The 2000 Garrod lecture. Factors impacting on the problem of antibiotic resistance**. *J Antimicrob Chemother* 2002, **49**(1):25-30.
12. Shadick NA, Phillips CB, Logigian EL, Steere AC, Kaplan RF, Berardi VP, Duray PH, Larson MG, Wright EA, Ginsburg KS *et al*: **The long-term clinical outcomes of Lyme disease. A population-based retrospective cohort study**. *Ann Intern Med* 1994, **121**(8):560-567.
13. Asch ES, Bujak DI, Weiss M, Peterson MG, Weinstein A: **Lyme disease: an infectious and postinfectious syndrome**. *J Rheumatol* 1994, **21**(3):454-461.
14. Zhang X, Meltzer MI, Pena CA, Hopkins AB, Wroth L, Fix AD: **Economic impact of Lyme disease**. *Emerg Infect Dis* 2006, **12**(4):653-660.
15. Cameron DJ: **Generalizability in two clinical trials of Lyme disease**. *Epidemiol Perspect Innov* 2006, **3**:12.